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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,466	11/26/2001	Ragupathy Madiyalakan	AREX-P03-002	7223

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EXAMINER
HUFF, SHEELA JITENDRA

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/994,466	MADIYALAKAN, RAGUPATHY	
	Examiner	Art Unit	
	Sheela J Huff	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-11,16-18,21-23,25-29,33 and 42-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2,5-11,16-18,21-23,25-29,33,42-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment filed on 11/10/04 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 1-2, 5-11, 16-18, 21-23, 25-29, 33 and 42-48 are pending.

The rejection of claims 1-15, 22 and 35-37 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's deposit.

The rejection of claims 16-19 under 35 U.S.C. 112, first paragraph, is withdrawn in favor of a new one.

The rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of applicant's amendment.

The rejection of claims 35-36 under 35 USC 101 is withdrawn in view of the cancellation of the claims.

The rejection of claims 34 and 37 under obviousness-type double patenting is withdrawn in favor of a new one.

The rejection of claims 30-32, 34-35 and 37-38 under 35 U.S.C. 102(b) as being anticipated by Spencer et al Cancer Letters 100(1996) 11-15 is withdrawn in view of applicant's amendment.

The rejection of claims 30, 32, 34-35 and 37-38 under 35 U.S.C. 102(b) as being anticipated by Spencer et al Cancer Letters 100(1996) 11-15 is withdrawn in view of applicant's amendment.

The rejection of claims 30-32 and 34-35 and 37-38 under 35 U.S.C. 102(b) as being anticipated by Price et al. Breast 2:3-7 (1993) is withdrawn in view of applicant's amendment.

The rejection of claims 30, 32-35 and 37-38 under 35 U.S.C. 102(b) as being anticipated by Price et al. Breast 2:3-7 (1993) is withdrawn in view of applicant's amendment.

The rejection of claims 30, 32-35 and 37-38 under 35 U.S.C. 102(b) as being anticipated by Devine et al BioEssays vol. 14 (1992) pp. 619-625 is withdrawn in view of applicant's amendment.

The rejection of claims 30-32, 34-34 and 37-38 under 35 U.S.C. 102(b) as being anticipated by Devine et al BioEssays vol. 14 (1992) pp. 619-625 is withdrawn in view of applicant's amendment.

The art rejection under 35 USC 103 is withdrawn in view of applicant's amendment.

Information Disclosure Statement

The information disclosure statement filed 11/10/04 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. Specifically, applicant is directed to 37 CFR 1.98 (b) (3) which requires a list of the following information for US applications: inventor, application number and filing date.

Applicant should note that the examiner has considered the US applications. However, if applicant wishes these to be listed on the face of the patent, applicant will to fully comply with 37 CFR 1.98.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

Claims 1-2, 5-11, 16-18, 21, 23, 25-29, 33, 42, 44-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

The claims can now be read in two different ways. The first way is that applicant is administering a composition comprising Alt-1. This is not new matter. The second way is that applicant is administering the anti-anti-idiotypic antibody (or Ab3), This is new matter because the specification does not contemplate the use of Ab3 to treat tumors.

Claims 1-2, 5-11, 16-18, 21, 23, 25-29, 33, 42, 44-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of Alt-1 to treat a tumor wherein the mammal generates an immune response to the administration of Alt-1, does not reasonably provide enablement for the use of anti-anti-idiotypic antibodies to Alt-1 or other antibodies that bind to the same epitope as Alt-1 to treat tumors. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in In Re Colianni, 195 USPQ 150 (CCPA 1977) and have been adopted by the Board of Patent Appeals and Interferences in Ex Parte Forman, 230 USPQ 546 (BPAI 1986). Among these factors are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the breath of the claims,
5. the amount of direction or guidance present, and
6. the presence or absence of working examples.

The following is an analysis of these factors in relationship to this application.

Applicant claims and discloses the use of anti-anti-idiotypic antibodies to Alt-1 or other antibodies that bind to the same epitope as Alt-1 to treat tumors. Applicant is climing the induction of an immune response to anti-anti-idiotypic antiobides to Alt-1. However, applicant has only shown the treatment of tumors using Alt-1. Claim 16 is included in this rejection because of the word “therapeutic”.

The state of the art shows that when the anti-idiotypic response is activated the resulting anti-anti-idiotypic antibodies (or Ab3) can react to the same epitope as that of Ab1 (see page 65 of Herlyn et al Cancer Immunol. Immunother (1996) 43:65-76). Applicant shows (with respect to Alt-1 as Ab1 only) that the epitope recognized by Ab3 can be different than that recognized by Ab1. Chatterjee et al (U.S. Patent 6,235,280 B1) teach that not all anti-idiotypic antibodies can be used in therapeutic regimens against tumors. First, only a fraction of antibodies raised against an Ab1 (anti-antigen antibody) are limited in their reactivity to the paratope of Ab1 (i.e., are non-reactive

against features shared with other potential antibodies in the host). Second, anti-idiotypic antibodies are not necessarily immunogenic. Third, only a fraction of the immunogenic anti-idiotypes elicit an antigen-specific immune response. Further, anti-idiotypic therapy with respect to tumor origin and antigens expressed should be evaluated on a case-by-case basis since different cancers have widely varying molecular and clinical characteristics (see column 2, lines 39-53). Furthermore, the state of the art is completely silent as to the use Ab3 antibodies to generate an immune response or treat any disorder.

While applicant has effectively shown this for Alt-1, applicant has not shown that anti-anti-idiotypic antibodies to Alt-1 or any other antibody that binds to the same epitope as Alt-1 can induce such an anti-idiotypic response. And even if such a response were produced, there is no objective evidence to show that tumors could be treated.

In view of the above, it is the Examiner's position that one skilled in the art could not make and/or use the invention without undue experimentation.

Response to Applicant' arguments to the extent that they read on this rejection

Applicant argues that working examples have been provided for the antibodies encompassed by the phrase "the antibody or antigen binding fragment thereof binds to an epitope to which a monoclonal antibody produced by a hybridoma having ATCC Designation Number PTA-975". The examples only show the use of Alt-1 to treat tumors. No other antibodies are exemplified.

Claims 16-18, 21-23, 25-29, 42, 44-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. In claims 16 (line 6), the terminology "immune response" has no proper antecedent basis. As stated in line 2 of the claim, applicant is producing "antibodies" not "immune responses". Changing "immune responses" to --antibodies-- will overcome this rejection.

b. In claim 16, line 7 "the antigen" has no antecedent basis. Inserting the words --multi-epitopic-- between "the" and "antigen" will overcome this rejection.

c. In claims 44-46, the terminology "the carbohydrate and peptide amino acid sequence" renders the claims vague and indefinite. The recited sequence only recited amino acids and no carbohydrate.

d. In claim 18 it is not clear if the "second epitope" can have some of the same amino acids as the first epitope or if the second epitope is completely different from the first.

e. In claim 16, it is not clear what the "therapeutic composition" is therapeutic for.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 5-11, 18, 21-23, 25-29, 33 and 43-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-16, 28-29 of U.S. Patent No. 6716966. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two sets of claims is that the epitope in patent is limited to the sequence DTRPAP and the epitope in the instant application is directed to a peptide comprising said sequence or is directed to a peptide that can be different than said sequence. The binding agent/antibody is obvious over the composition because the composition merely recites the antibody/binding agent and no other component.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Price et al. Breast 2:3-7 (1993).

This reference discloses non radiolabeled antibodies against polymorphic epithelial mucins (PEM) (see entire reference). This reference discloses anti-PEM antibodies other than HMFG-1 which bind to a sequence in the APDTRPAP (specific epitopes are given in the Table on page 4). These antibodies have been used in immunoassays (see abstract) (thus reading on composition). It is inherent that the antibody can treat a tumor that expresses a tumor-associated MUC1.

Response to Applicant' arguments to the extent that they read on this rejection

Applicant argues that the cancellation of the rejected claims obviates the rejection. This is now added to the rejection, because when the previous was completed, claim 33 depended upon claim 36 (which was improper) and the limits of the claim 33 could not be fully evaluated at that time.

Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by Devine et al BioEssays vol. 14 (1992) pp. 619-625.

This reference discloses antibodies to Mc1, BrE1, HMFG1, and F36/22 and B72.3, SH1 and that these ab have been used in therapeutic application to target and reduce tumor growth (see page 624, first column) and in diagnostic applications (see top of Table 4).

Response to Applicant' arguments to the extent that they read on this rejection

Applicant argues that the terminology "consisting essentially of" excludes other active ingredients. Applicant is arguing limitations not in the claims. Additionally, the

terminology "consisting essentially of" has not defined in the specification. Applicant is cautioned against the addition of new matter.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Mondays and Thursdays from 5:30am to 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheela J Huff
Primary Examiner
Art Unit 1642

sjh